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EXAMINER	ART UNIT	PAPER NUMBER
DUDASH, T	1112	5

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DATE MAILED: 03/30/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 9 - 14 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1 - 8 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 9 - 14 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 08/173,542; filed on Dec 22, 1993.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Serial Number: 08/346,066

Art Unit: 1112

Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 9-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 are vague and indefinite due to non-idiomatic English such as "done over", "doing over", "a lifting medium". Claim 9 lacks antecedent bases for "the assembly tube plus stent", line 9, and "the layer covered portion", line 15. The claim is also vague and indefinite as "allowing the stent to radially expand" is not a positive recitation that the stent expands. Claim 9 is further vague and indefinite due to "a sufficient amount of solvent to permit wet forming". Wet forming of what? Further, "to permit" is not positive recitation of wet forming. Claim 10 is confusing due to "is first wetted alone with the elastomeric composition added with solvent". If the elastomeric composition has solvent added then how is it being used alone? Further, according to claim 9 the elastomeric composition is already dissolved in solvent. Is the solvent of claim 10 additional solvent or the same as in claim 9? Claim 11 is vague and indefinite due to "doing over a roll on surface", as it is unclear if applicant is referring to a roll on a surface,

and if so, what surface? Further, it is unclear how the stent can be withdrawn from the roll on surface because it appears that the stent is merely placed on the roll on surface, not in it. Claims 11 and 14 are vague and indefinite due to "contact forming". Claims 12-14 are vague and indefinite due to "predetermined", which merely means determined beforehand. See Joseph E. Seagram & Sons, 84 U.S.P.Q. 180. Claims 12-14 are further vague and indefinite due to "corresponding to said predetermined length". How does the portion of the stent correspond to the length of the tube? Claim 12 is vague and confusing due to "welding the surfaces of contact between the stent and the tube". How are the contact surfaces welded if they are between the stent and the tube?

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention

were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

3. Claims 9-11 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Stoy et al. taken with MacGregor '253 and further in view of Montgomery '312.

Stoy et al teach methods of making guidewires which have a non-hydrogel core(inner) element and an integral outer tubular layer of elastomeric hydrogel (Abstract). Guidewires are designed to facilitate the placement of various tubular devices, such as stents and catheters. The problem of friction with surfaces, such as vascular walls and the inner walls of catheters, has been addressed in the art by applying low friction coatings, e.g. PTFE or hydrogels, to the guidewires(col.1, line 31-col.2, line 65). Stoy et al teach use of an elastomeric hydrogel outer tubular layer, which may be applied by melt extrusion directly onto the core, in situ hydrogel formation, and tubing extrusion followed by shrink fitting over the core. (col.4, lines 1-24,51-68). They teach that adhesion of the hydrogel layer to the core has been a problem in the art (col.3, lines 26-61). They also teach applying the hydrogel sleeve on the core element, or a portion thereof, which has a larger outer diameter than the inner diameter of the sleeve by temporarily swelling the sleeve. This is similar to the instantly claimed methods whereby a similar change is accomplished by contracting

the inner member, instead of enlarging the outer member (col.6, lines 1-60). They teach alternatives wherein the resulting sleeve is firmly attached without adhesives or other bonding means or the radial stress can be supplemented and/or replaced by use of various adhesives. The reference lack radially contracting a stent in order to insert it into a tube and is directed to guidewires, however it is the Examiner's position that the various problems involved in making and using guidewires are analogous to the problems of catheters and stents. If applicant disagrees he should so state for the record. The reference also lacks welding or a specific method of applying the disclosed adhesives.

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within a tubular body, such as a catheter (col. 1, line 65-col.2, line 50). They teach use of biocompatible and hemocompatible adhesives in manufacturing the stents, and further teach enhancing the stent by coating the exterior surface of the stent. MacGregor discusses using frangible materials to form the bonding point to facilitate expansion of the stent.

Montgomery teaches a process of coating whereby a first crosslinked lubricant is coated onto a surface such as a syringe barrel and a second lubricant is applied over the first. A second surface, such as a syringe stopper, is engaged with the

first surface. See abstract, col.1,line 13- col.2, line 48; col.3, lines 38- 54; col.4, lines 48-57; Ex. I. The lubricant compositions may both contain solvents and may be crosslinked after application.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process of Stoy by compressing a stent before inserting it into a tube for coating, as suggested by MacGregor, because of the expectation of ease of insertion as well as preventing squeezing the coating out of the tube. Further, it would have been obvious to apply a lubricant composition to the inside of the outer tubular member before applying the coating solution thereto, as suggested by Montgomery, because of the expectation of reducing the friction between the two members.

4. Claims 12 and 13 are rejected under 35 U.S.C. § 103 as being unpatentable over Stoy et al., MacGregor and Montgomery as applied to claims 9-11 and 14 above, and further in view of Meyers. The references lack the welding and adhering methods of the instant claims, though Stoy teaches use of adhesives to adhere the outer hydrogel coating he does not teach any specific application methods.

Meyers teaches connecting two plastic pipes by inserting the male end into the female end of a plastic pipe which has a

solvent weld glue applied at the inner surface thereof (Abstract; col.1, line 55-col.2, line 19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process of the combined references by use of weld glue applied to the interior of a polymeric outer tube, as suggested by Meyers, given the general teaching on use of adhesive in Stoy, because of the expectation of successfully welding/adhering the two tubes together.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stobbie, IV et al, teach adhesively bonding a hollow first member to a second member received interiorly of the first. Adhesive is applied to the second member and allowed to attain a substantially non-flowable condition before the members are positioned such that the first member at least partially overlies the adhesive(Abstract). Stobbie et al. also describe an adhesive dispenser which comprises a die having a series of grooves and ridges on its interior surface for distributing the supply of adhesive(col.1, line 62-col.2, line 16).

Anderson et al '179 teaches coating of catheters having polymer surfaces in face-to-face contact with a thin film of PTFE

to prevent adhesion of the contacting surfaces(Abstract; col.4, lines 7-47).

Information Disclosure Statement

6. The information disclosure statement filed November 29, 1994 fails to comply with 37 CFR § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Dudash whose telephone number is (703) 308-2328.

Diana L. Dudash
Patent Examiner
Group 1100

dld
March 23, 1995